DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

October 4, 2001

Our Reference: 2953449

Glynn A. Ross, President
Marina Seafoods, Inc.
74-425 Kealakehe Parkway, No. 17
Kailua-Kona, Hawaii 96740

WARNING LETTER

Dear Mr. Ross:

We inspected your seafood processing facility, located at the above address, on July 20 and 24, 2001. We conducted this inspection to determine your compliance with FDA's seafood processing regulations Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deviations. These deviations cause your histamine forming species such as tuna, Mahi-mahi, Marlin, and Wahoo, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that the fish have been prepared, packed or held under insanitary conditions whereby they may be rendered injurious to health. We listed the deviations on a Form FDA 483 (Inspectional Observations) and discussed them with you at the conclusion of the inspection. Your serious HACCP deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a written HACCP plan for histamine forming species such as tuna, Mahi-mahi, Marlin, and Wahoo, to control the food safety hazard of histamine formation as a result of time/temperature

abuse. During our inspection, we collected and analyzed a sample of vacuum packed hot smoked Ahi tuna. Our analyses showed that the product was decomposed and contained high histamines [161, 200, and 825 parts per million (ppm) original analysis, and 190, 210, and 763 ppm check analysis]. The finding of these levels of histamine in your product indicates a failure in your preventive system and requires immediate reassessment of your seafood operations. Fish is adulterated within the meaning of Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act if it contains histamine, a poisonous and deleterious substance, in such quantity that may render it injurious to health. For your information, histamine level equal or greater than 500 ppm is considered a danger to health. We acknowledge that the remaining portion of this lot was ultimately destroyed during the inspection.

2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the following areas of sanitation to ensure control:

   (a) Safety of water.

   (b) Protection of food from contamination – FDA observed during the inspection that tuna fish were held directly on the floor.

   (c) Employee health conditions.

   (d) Exclusion of pest from the facility.

During the first day of the inspection, we performed organoleptic examinations on some of the fish (whole and filleted) held in your chill unit. We found a partial piece of shark and two whole Mahi-mahi to be decomposed. During the second day of the inspection, on July 24, 2001, we again performed organoleptic examinations on some of the fish stored in your chill unit and found five (5) whole spearfish to be decomposed. These decomposed fish were all voluntarily destroyed during the inspection. Fish is adulterated within the meaning of Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act, if it is entirely or partially decomposed. Your product must not be adulterated and they must be manufactured under Current Good Manufacturing Practices.

You must immediately take appropriate steps to correct these deviations. We may initiate regulatory action without further notice if you do not correct them. For

instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen working days from receipt of this letter. Your response should outline the specific things you are doing to correct the deviations. You may wish to include in your response documentation such as your HACCP plan and copies of completed monitoring records, or other useful information that would assist us in evaluating your corrections. Additionally, your reply should include the steps that you have taken to preclude distribution of decomposed fish. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District